MECHANICS

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Mechanical and finite element models of corneal keratoprostheses

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Introduction. When developing ocular prostheses, a number of problems arise, one of which is the construction of the connection between the hard optical part and the soft corneal tissue. Their Young's modules can differ by three orders of magnitude. In this case, the problem arises of creating an intermediate layer, possibly with gradient properties, whose purpose is to exclude injury to soft biological tissues. Two types of keratoprostheses are considered: the first type with a support plate and the second type with an intermediate functionally gradient layer. The stress-strain state of the prosthesis is calculated for the first type. For the second type, analytical and finite element modeling of the interaction of a cylindrical optical prosthesis, an intermediate inhomogeneous layer, and the cornea was carried out in the elastic media. Two versions are considered: discounting the curvature (circular plate or plate) and with account of the curvature (spherical dome or shell). The work objective is to study the stress-strain state of the keraprosthesis and cornea in the contact area.
Materials and Methods. Mathematical models of the structures under consideration are the boundary value problems of the linear elasticity theory. The analytical solution is constructed for a simplified model in the form of a composite circular plate. Spatial three-dimensional problems and axisymmetric problems are solved by the finite element method. Finite element modeling of the considered structures was performed in the CAE package ANSYS and ACELAN.
Results. CAD models of keratoprostheses with conditions of fixing and loading are constructed. The load acting on the keraprosthesis under the effect of intraocular pressure was determined. The stress-strain state of the keratoprosthesis and cornea elements was calculated. Special attention was paid to the area of its contact with the keratoprosthesis.
Discussion and Conclusions. The results of calculating the axial displacements and mechanical stresses in the first type of keratoprosthesis show that the selected geometric parameters meet the kinematic and strength requirements. The proposed models of the deformed state of soft biological tissues provide assessing their injury when using a keratoprosthesis of the second type, as well as selecting the geometric parameters and gradient properties of the intermediate layer.

***Keywords**:* ocular prosthesis, inhomogeneous elastic properties, plate, shell, finite element method.

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Introduction. A keratoprosthesis (KPro) is a cell-free artificial implant designed so that a cylindrical frame holds the optics. Keratoprosthesis replaces the removed part of the cornea. Previously, corneal transplants had high rates of infection and rejection. In the late 1980s, the “core-skirt” design (a bio-integrated “skirt” surrounds the optics) was the most widespread one. Not only the sizes, but also the location of the pores in the porous skirt were important. Keratoprostheses, such as AlphaCor (formerly known as Chirila), were polymethylmethacrylate devices with a central optical region fused to the surrounding porous skirt.

Modern keratoprostheses consist of an optical element and a supporting plate. The optical transparent element has the shape of a cylinder or lens. The supporting plate connected to the optical element can have various shapes: a ring with holes, a spoked wheel, ears, or amoeboid legs. The book by S. N. Fedorov [1] describes various types and

forms of keratoprostheses and fasteners. The main complication after keratoprosthetics is aseptic necrosis of the cornea which develops in front of the supporting attachment of the implant. This complication often causes rejection of the keratoprosthesis [1]. The major cause of aseptic necrosis is blocking the flow of vital substances into the layers of the cornea, which are located above the keratoprosthesis support. In this regard, for the manufacture of the supporting plate, it is required to use a biocompatible material that will allow corneal tissues to grow through the supporting mount.

American researchers have described a microporous support plate[1] for keratoprosthesis made of stretched polytetrafluoroethylene (PTFE). Its structure has a configuration in the form of polymer nodes, which are connected by fibrils 7-8 μm long. Too small pores prevent the corneal tissue from ingrowth. Therefore, it is required to additionally penetrate the prosthesis with pores perpendicular to the surfaces of the supporting plate with a diameter of 20-150 μm (preferably 50 μm). The thickness of the supporting plate should be about 0.2 μm, but not more than 0.3 μm.

In the model with a ring-shaped[2] supporting attachment, the optical element is made of a transparent substance such as polymethylmethacrylate (PMMA), the attachment is made of a hydrophilic porous material with fibrous structure through which corneal tissue can ingrow. A supporting plate with a thickness of 0.15–0.30 μm is formed from this fiber. A ring with an external diameter of about 9.5 mm is placed on the optical element. Its front part is cylindrical, the back has a conoid, whose larger section is directed inward. The supporting plate has elastic characteristics required to prevent rejection of the keratoprosthesis and necrosis due to the pressure of the surrounding eye tissues.

In another design[3], the supporting plate consists of two parallel shells spaced 0.4–0.7 μm apart. The optimal distance is 0.3±0.02 mm. Conical shells are attached to a cylindrical optical element. The material of the supporting plates should be bio-populated; therefore, it is assumed that its porosity is 50% or higher, the pores should be open, and their diameter is about 20–100 μm.

Elements of the keratoprosthesis[4] proposed by Russian scientists (Fig. 1) are as follows:

— supporting plate — 1 (radius of curvature is 7–10 mm, external diameter is 7–12 mm);

— optical part — 2 (optical element in the form of a cylinder with rounded ends that serve to select diopters);

— cylindrical surface of the optical threaded element — 3;

— connecting washer — 4 (rigidly attached to the supporting plate).

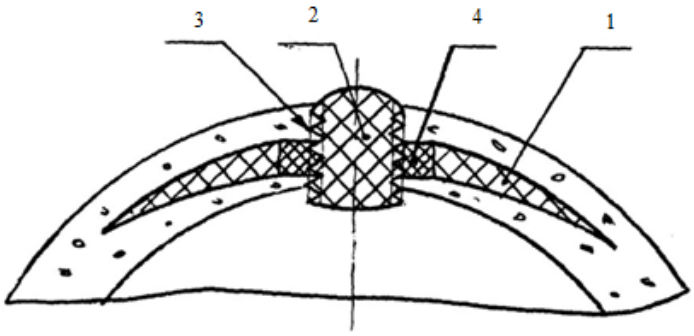


Fig. 1. Scheme of keratoprosthesis

The keratoprosthesis is implanted in the intralamellar corneal pocket. The supporting plate is located inside the cornea, and the optical element penetrates the entire cornea.

The implant for strengthening the cornea[5] is a plate — round, oval, in the form of a shamrock, chamomile, or convex-concave lens with a curve radius of 7–10 mm. There may be a cylindrical hole in the center of the lens. In the structure of the implant material, the volume void rating is 15–40 %, their specific surface area is 0.25–0.55 $mm^2/\mu m^3$, the average distance between voids is 25–50 μm, and the mean volume chord is 8–25 μm. The implant is a convex-concave lens whose curve radius corresponds to the curve radius of the patient's cornea. In the central part, the implant thickness is 0.3–0.7 mm, and it is 0.01 mm at the edges.

In another modification of the keratoprosthesis[6], in contrast to the one described above, the supporting block is made of porous titanium nickelide, the curvature of the plate coincides with the curvature of the cornea. The supporting plate is installed on the surface of the cornea and is retentively fixed with a sclera allograft. The cylindrical optical element is connected to the supporting plate by a tight fit method. This approach enables to treat leukomata more effective-

[1] US Patent no. 5713956, M. cl. 7 A 61 F 2/14, 1998.
[2] US Patent no. 5489301, M. cl. 6 A 61 F 2/14, 1996.
[3] US Patent no. 6106552, M. cl. 7 A 61 F 2/14, 2000.
[4] Keratoprosthesis. RF Patent no. 2270643, 2006. (In Russ.)
[5] Implant to strengthen the cornea. RF Patent no. 2270642, 2006. (In Russ.)
[6] Keratoprosthesis and method of surgical treatment with its help. RF Patent no. 2367379, 2009. (In Russ.)

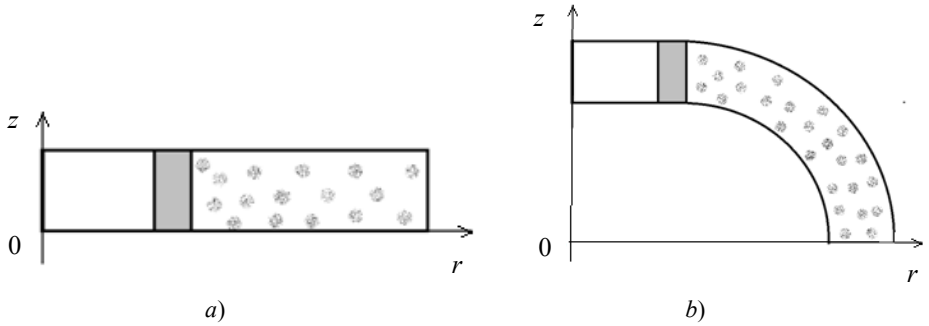
ly, thanks to the rapid and successful integration of the porous implant (base) with the surrounding tissues and mechanically strong fixation of the optical element, which reduces the risk of keratoprosthesis reposition.

The developer of the combined keratoprosthesis[1] notes that the supporting part of the implant should maximally resist pushing pressure of the intraocular fluid on the optical part of the keratoprosthesis and minimally deform the appropriate tissues. The material of the supporting part should not only be biocompatible, but also structured so as to provide the fusion of the above and below layers of the cornea, which are separated during the implantation of the keratoprosthesis. Keratoprostheses with an optical element made of a transparent substance (for example, PMMA) and a supporting plate in the form of a ring made of hydrophilic porous material PTFE or polyethylene[2] were fore-mentioned. Their use provides fusion of the above and underneath layers of the cornea due to the high porosity of the material (from 50 %) and the pore diameter up to 100 μm. The main disadvantages of such structures are excessive flexibility and low mechanical strength. These characteristics do not provide reliable retention and fixation of the installed keratoprosthesis with large optics for a long time.

The optical part of the combined keratoprosthesis is made of a transparent elastic polymer saturated with UV adsorbent. In shape, it is a removable bolt with a diameter of 5–6 mm. The front end is fungiform, while the others are spherical (aspherical). The haptic part is a supporting disk with an outer diameter of 8–12 mm and a thickness of 0.3–0.9 mm. Its side surface is threaded. For this part, a porous (perforated) solid (elastic) areactive polymer (metal) with a volume void rating of no more than 50 % is used. The front part of the haptic is made of biological materials, the back part is made of artificial biocompatible materials. The supporting disk of the back part is flat and connects perpendicularly to the supporting hollow cylinder located in the center. The connection is provided by a groove and / or flange on the outer rear of the cylinder. The profile and diameter of the internal thread of the cylinder correspond to the thread of the optical bolt. The support disk can pass into a sleeve that wraps around the supporting cylinder from the outside. The supporting plate is connected at the front with a round biodisc, which is cut out of freshly removed or preserved sterile biological materials. They are multi-layered combinations of biological tissues. Before joining, parts of the keratoprosthesis are sterilized. The connection is carried out under sterile conditions. Assembly is performed immediately before prosthetics or in advance (in this case, the implant is stored until the surgery). The external diameter of the biodisc should be greater than the external diameter of the supporting disk by 0.3–1 mm. In the center of the biodisc, a coaxial bore is made with a diameter corresponding to the outer diameter of the cover sleeve or the supporting cylinder.

For penetrating keratoplasty, models are developed using various materials, structures, and surgical methods [2]. However, the problem is not completely resolved. This is confirmed by cases of corneal blindness in patients with repeated graft failure or severe damage to the eye surface [3–6]. The issues of keratoprosthetics in diseases of the cornea and ocular surface are considered in [7]. Review on the application of Boston KPro is presented in [8]. In [9], complications with wide consequences in the use of keratoprostheses are discussed.

In this paper, we consider two types of keratoprostheses with a cylindrical optical element. The diagram of the first type is shown in Fig. 1. In the second type, there is some intermediate layer with non-uniform mechanical properties on the cylindrical surface. Fig. 2 shows a diagram of the half-axial section of the second-type KPro disregarding the curvature (a) and with account for the cornea curve (b). The layer with functionally gradient properties is greyed out. It is needed for non-traumatic contact of the optics with the soft tissue of the cornea.



a) *b*)

Fig. 2. KPro half axial section: plate model (a), dome model (b)

Analytical and numerical models of keratoprosthesis implantation in the cornea are constructed using the finite element method. The stress-strain state of the cornea in the contact area is studied. This defines the objectives of this work. For the first-type KPro, they include investigations on its stress-strain state under the action of intraocular pressure, assuming that the outer edge of the supporting plate is fixed. The objectives for the second-type KPro are to study

[1] Combined keratoprosthesis. RF Patent no. 2707646, 2019. (In Russ.)
[2] US Patents no.5489301, no. 6106552.

the stress-strain state of the cornea in the vicinity of the contact with the keratoprosthesis, whose outer layer is a structure that reduces soft tissue injury. This intermediate (interface) layer is modeled as a hollow cylinder with functionally gradient mechanical properties.

Three models are considered in the paper.

I. Analytical — for an implanted prosthesis based on the bending of a composite circular plate.

II. Finite element — for an implanted prosthesis based on a composite circular plate.

III. Finite element model — for an implanted prosthesis based on a composite spherical dome.

Modeling problems are solved for:

— keratoprosthesis of the first type (A),

— keratoprosthesis of the second type (B).

Materials and Methods. The continual formulation of the tasks. The general mathematical formulation of the problem under study (for problems A and B) is a static boundary value problem of elasticity theory for a composite isotropic body.

For the unknown $\vec{u} = (u_1, u_2, u_3)$ of the displacement vector component, the system of differential equations has the form [10]:

$$\sigma_{ij,j} = 0\,,\ \varepsilon_{kl} = \frac{1}{2}(u_{k,l} + u_{l,k})\,, \tag{1}$$

where σ_{ij}, c_{ijkl}, ε_{kl} are components of stress tensors, elastic constants, and deformations, respectively.

Boundary conditions are set for the displacement and stress vectors on the corresponding surfaces S_u and S_t:

$$u_i\,|_{S_u} = u_i^0(\overline{x}, t),\ \ \overline{x} \in S_u\,, \tag{2}$$

$$t_i\,|_{S_t} = \sigma_{ij} n_j\,|_{S_t} = q(\overline{x}, t),\ \ \overline{x} \in S_t\,, \tag{3}$$

where n_j are coordinates of the outer normal unit vector.

In addition, for problem B (see Fig. 2) subbodies have different properties, namely:

— two of them (cylindrical optical prosthesis and cornea) are homogeneous, with elastic moduli Er_1 and Er_3;

— functionally gradient elasticity modulus of the interface layer — $Er_2 = Er_2(r)$.

The right side is fixed, and the left side has symmetry conditions. The lower boundary is affected by uniform pressure, which corresponds to excessive intraocular pressure compared to atmospheric pressure. On the interface boundaries, continuity conditions are set.

To study the model (I), the boundary value problem (1) – (3) is reduced to a system of ordinary differential equations (4), (5), and (6) for the first, second, and third sections, respectively, relative to the angle of rotation of the normal with a power-law dependence on the radius of the elastic modulus of the second section [11]:

$$\left(\frac{d^2}{dr^2}\theta(r)\right)r^2 + \left(\frac{d}{dr}\theta(r)\right)r - \theta(r) = \tfrac{1}{2}Klqr^3, \tag{4}$$

$$\left(\frac{d^2}{dr^2}\theta(r)\right)r^2 + a\left(\frac{d}{dr}\theta(r)\right)r + a\vartheta_2\theta(r) + \left(\frac{d}{dr}\theta(r)\right)r - \theta(r) = \tfrac{1}{2}\frac{K_2 q(r^2 - r_1^2)r^{2-a}}{r}, \tag{5}$$

$$\left(\frac{d^2}{dr^2}\theta(r)\right)r^2 + \left(\frac{d}{dr}\theta(r)\right)r - \theta(r) = \tfrac{1}{2}K3q(r^2 - r_2^2)r, \tag{6}$$

where $K = 1/D$, D is cylindrical stiffness.

Research Results

Analytical solution

General solution to the system (4) – (6) is presented below.

The first section:

$$\theta(r) = rC_2 + \tfrac{1}{16}Klqr^3 + \tfrac{C_1}{r}.$$

The third section:

$$\theta(r) = \tfrac{C_1}{r} + rC_2 - \tfrac{1}{16}K3q(4\ln(r)r_2^2 - r^2)r. \tag{7}$$

The second section:

$$\theta(r) = r^{-\frac{1}{2}a + \frac{1}{2}\sqrt{a^2 - 4a\vartheta_2 + 4}}C_2 + r^{-\frac{1}{2}a + \frac{1}{2}\sqrt{a^2 - 4a\vartheta_2 + 4}}C_1 + \\ + \frac{1}{2}\frac{K_2 q r^{1-a}\left(((r^2 - r_1^2)\vartheta_2 - r^2 + 3rl^2)a - 8rl^2\right)}{(8 + (\vartheta_2 - 3)a)a(\vartheta_2 - 1)}$$

at

$$Er_2 = Er_1\left(\frac{r_1}{r}\right)^a;\ D_2 = \frac{Er_2 h_2^3}{12(1-\vartheta_2^2)},\ a = \frac{\ln(\frac{Er_1}{Er_2})}{\ln(\frac{r_2}{r_1})}$$

Arbitrary constants C_i of the general solution (7) are determined from the boundary conditions at the right end and the blending conditions, and $C_1 = 0$ for the first section.

Finite element solution

Numerical simulation was performed in finite element packages ANSYS and ACELAN [12, 13].

Numerical results for KPro of the first type. Fig. 3 shows a CAD model of the keratoprosthesis with the conditions of fixing and loading.

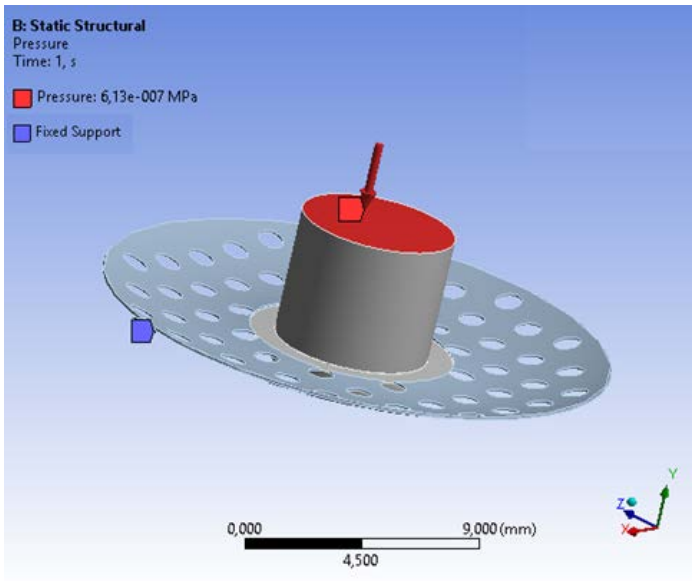
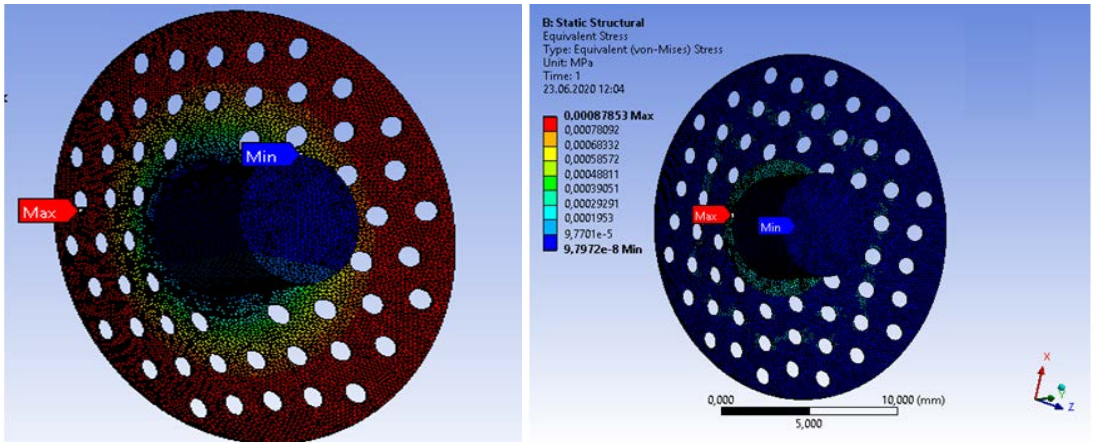


Fig. 3. Geometric model with fixing and loading conditions

The outer edge of the supporting plate is fixed, and the optical element is affected by distributed pressure. Normal intraocular pressure is between 12 and 21 mm/Hg. The pressure of 45 mm/Hg is critical. In this case, an operation can still save the eye. With higher pressure, it is almost impossible to save the eye. The current keratoprosthesis has actual load of 46 mm/Hg.

Fig. 4 shows the distribution of the axial displacement (*a*) and von Mises stress (*b*) on the finite element grid of the model.

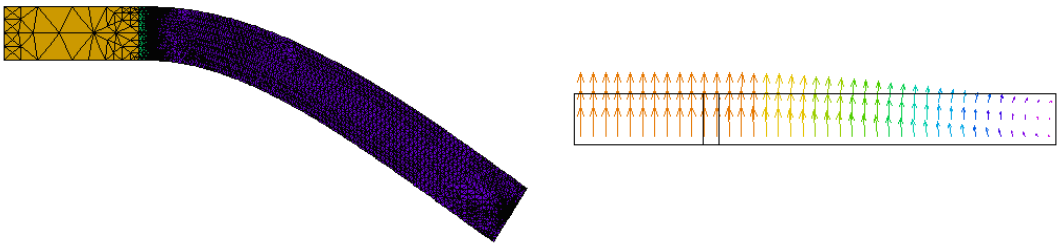


a) *b*)

Fig. 4. Distribution of the stress-strain state characteristics on the finite element model: axial displacement (*a*) and stresses according to von Mises (*b*)

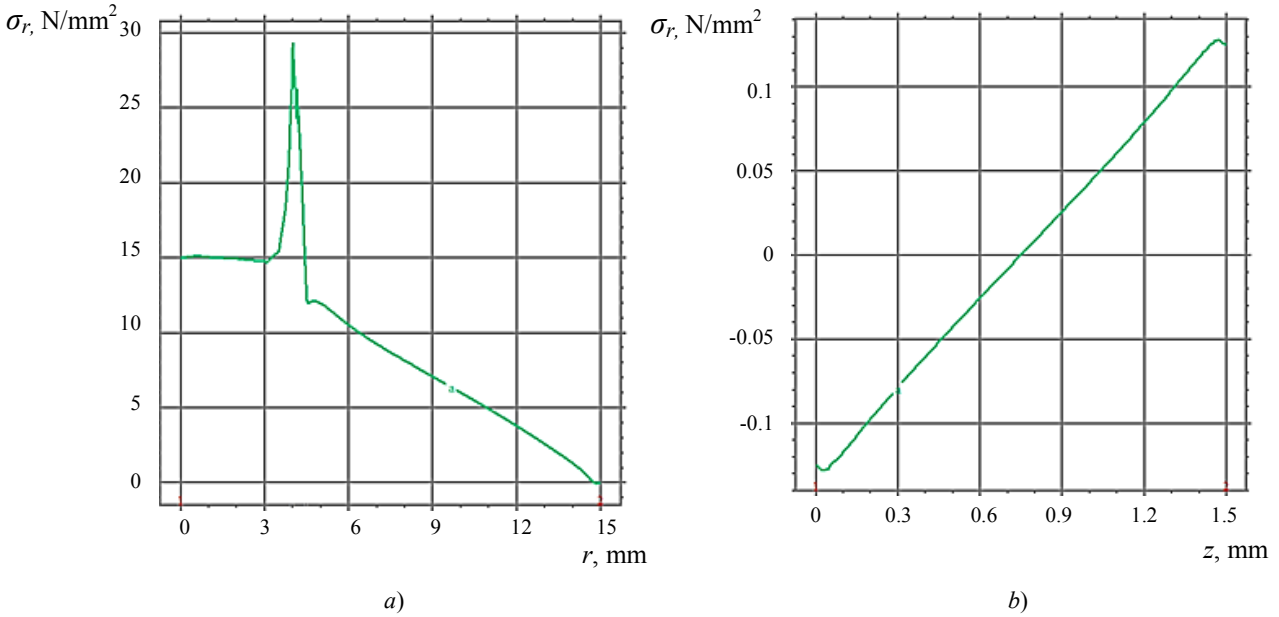
Maximum stresses occur at the junction of the optical element and the supporting plate, but their values do not exceed the strength limit of the selected material.

Next, we consider the calculation results for problem B in the axisymmetric formulation. So, Fig. 5–7 show the components of the stress-strain state (II).

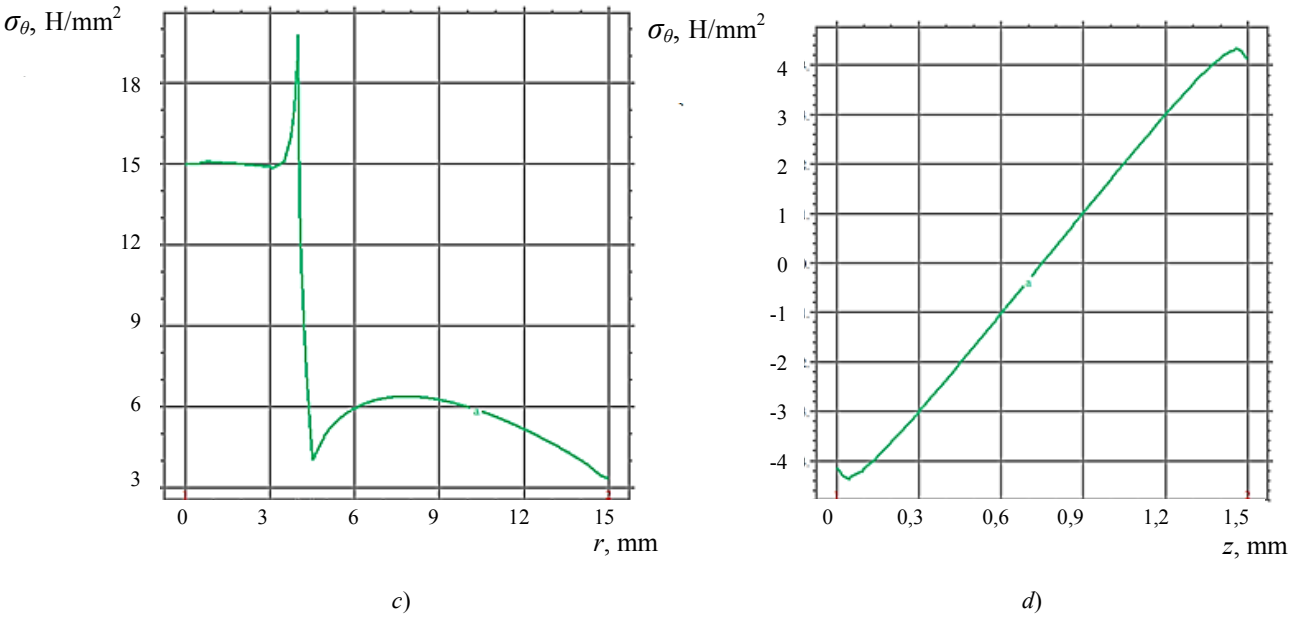


a) *b*)

Fig. 5. Calculation of displacements: finite element grid on a deformed structure (*a*), distribution of the displacement vector (*b*)



a) *b*)



c) *d*)

Fig. 6. Calculation of stress tensor components. Dependence on radius: radial stresses at the upper boundary (*a*), at the interface boundary with the cornea (*b*), angular stresses at the upper boundary (*c*), at the interface boundary with the cornea (*d*) N/mm^2

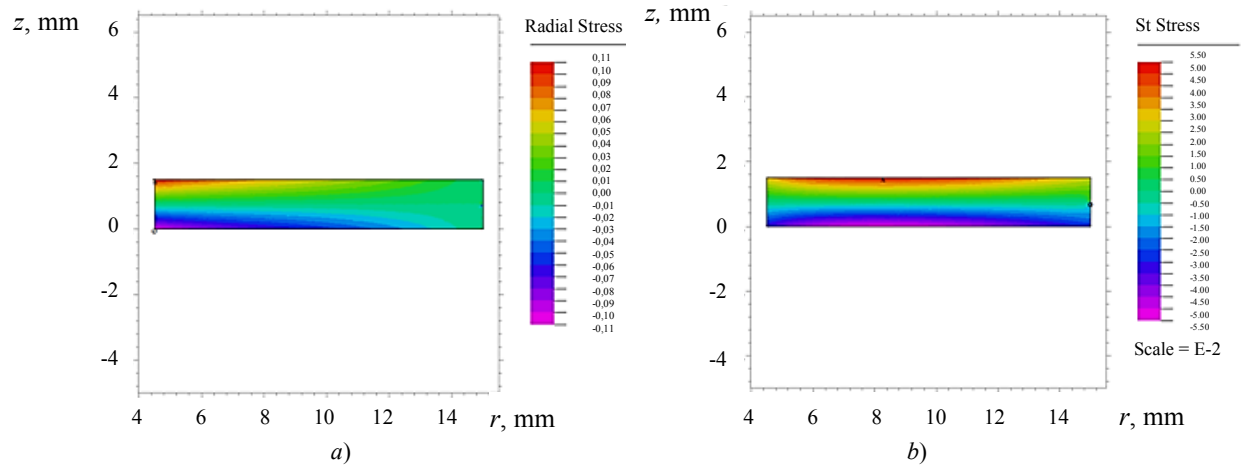


Fig. 7. Distribution of components of stresses inside the area: radial stresses (a), angular stresses (b)

The stress-strain state characteristics of model III are shown in Fig. 8–11

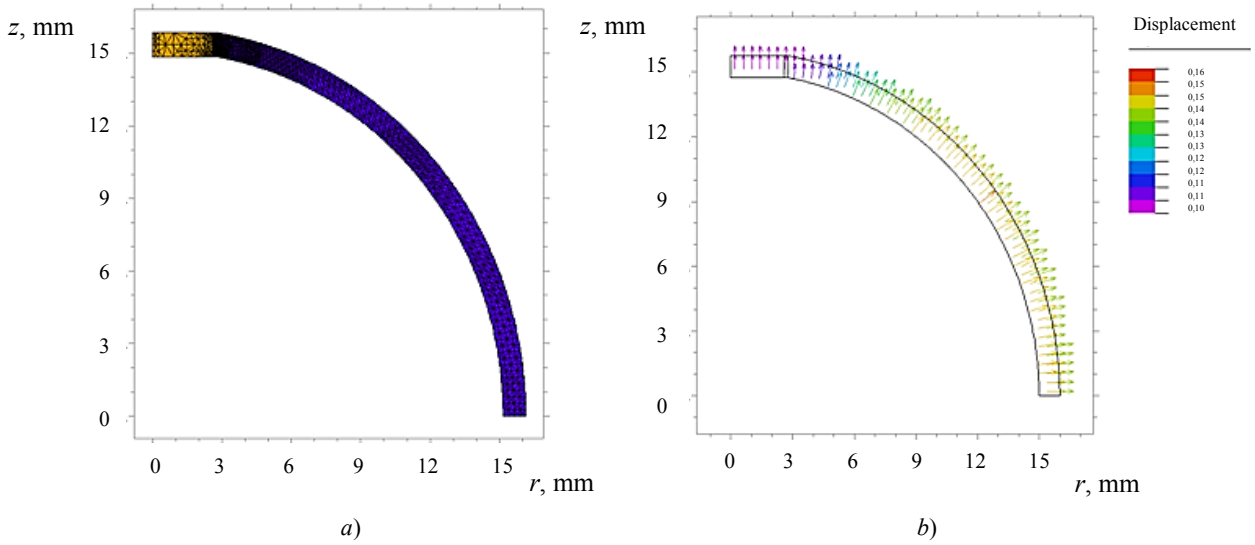


Fig. 8. Calculation of dome displacements: finite element grid on deformed structure (*a*), distribution of the displacement vector (*b*)

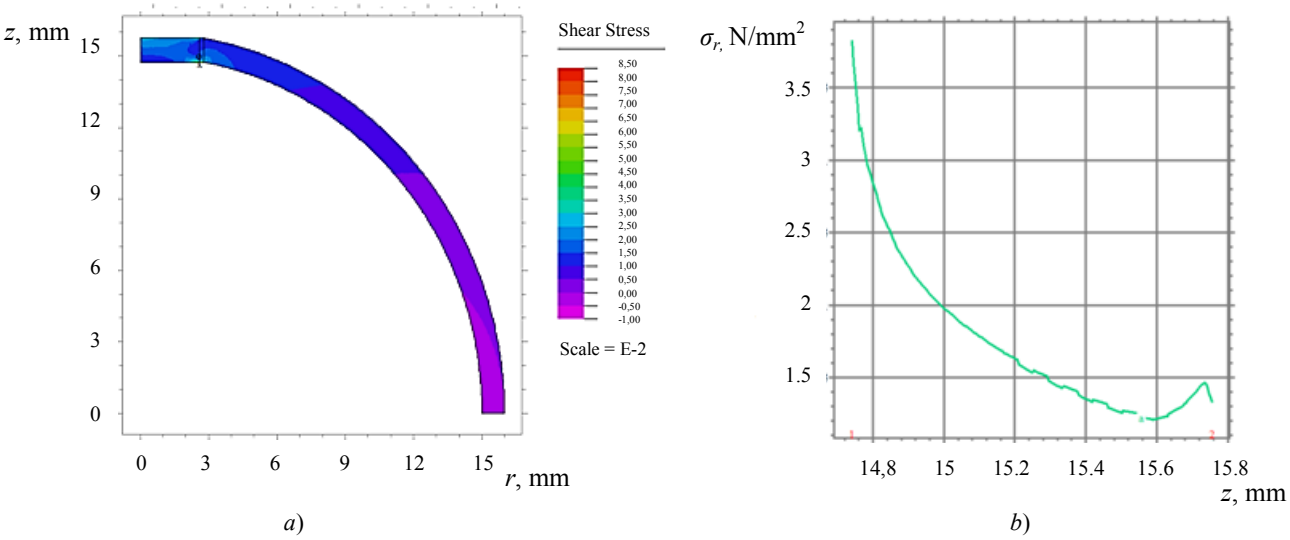
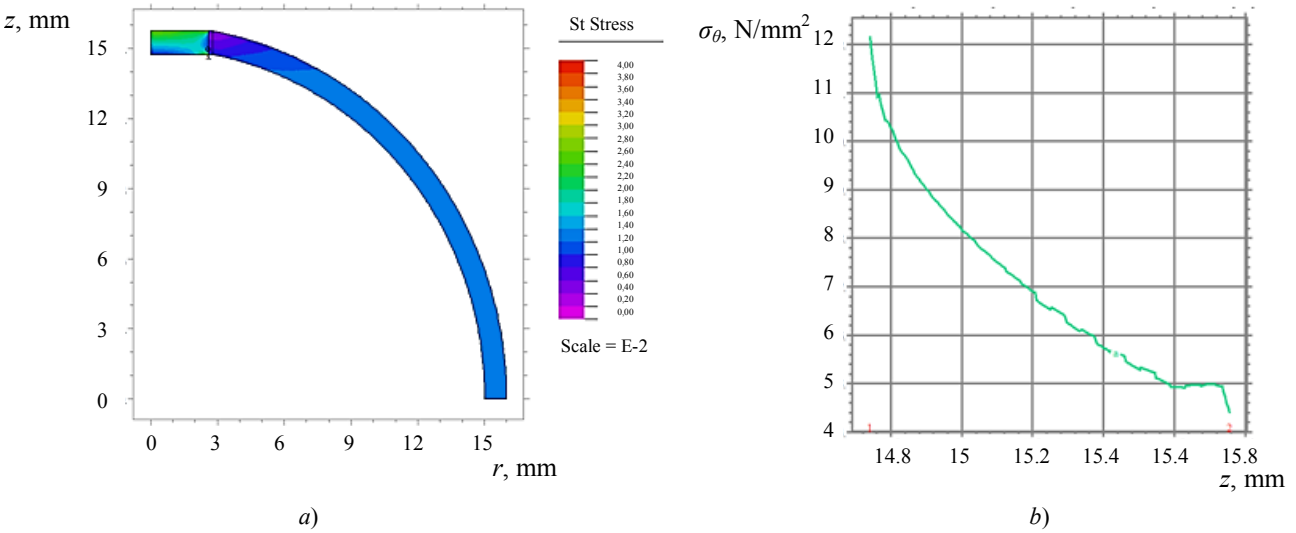
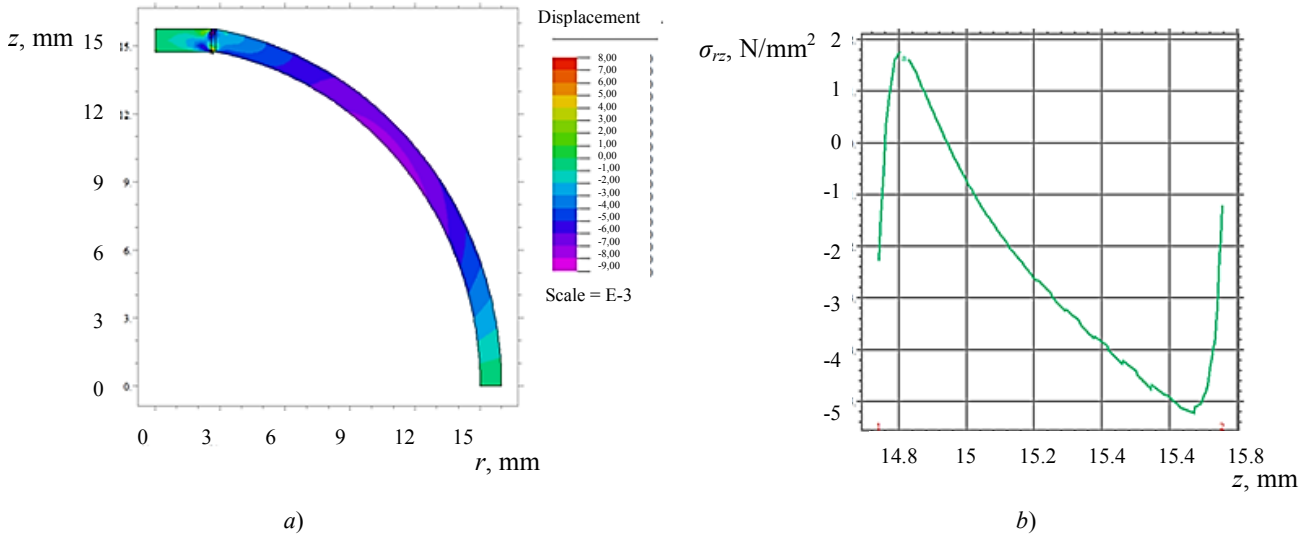


Fig. 9. Calculation of radial stresses: distribution in the region (*a*), at the interface border with the cornea (*b*)



a) *b*)

Fig. 10. Calculation of angular stresses: distribution in the region (*a*), at the interface border with the cornea (*b*)



a) *b*)

Fig. 11. Calculation of shear stresses: distribution in the region (*a*), at the interface border with the cornea (*b*)

Discussion and Conclusions. Two types of keratoprostheses are considered, and their mechanical and mathematical models are constructed. For the first type of KPro with a supporting plate, its stress-strain state was studied, and a finite element model was created in ANSYS. It is shown that at maximum eye pressure, the resulting maximum stresses do not exceed the strength limits of the selected materials. For the second type of KPro, an analytical solution disregarding curvature and a finite element solution in the ACELAN package with corneal curve are constructed. The characteristics of the stress-strain state, including those at the interface border with the cornea, are calculated. This provides evaluating its injury and selecting geometric parameters and gradient properties of the intermediate layer.

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Claimed contributorship

A. N. Soloviev: general statement of tasks; selection of research methods and programs; analysis of results. N. I. Glushko: conducting a review; building an approximate solution, finite element models in ACELAN; computational analysis. A. N. Epikhin: description of the keratoprostheses designs. Michael Swain: general statement of tasks. O. N. Lesnyak: building finite element models in ACELAN; computational analysis; correction of the text. A. E. Ivanov: building finite element models in ACELAN; computational analysis.

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